SUMMARY OF SAFETY AND EFECTIVENESS DATA
FOR A SUPPLEMENTAL PREMARKET APPROVAL APPLICATION

I. GENERAL INFORMATION

Device Generic Name:	RF Electrosurgical Device
Device Trade Name:	ViewPoint™ CK System
Applicant's Name and Address:	Refractec, Inc. 5 Jenner, Suite 150 Irvine, California 92618 USA (949) 784-2600 (949) 784-2601 (fax)
Date of Panel Recommendation:	February 6, 2004
PMA Number:	P010018/S5
Date of Notice of Approval to Applicant:	

The Refractec, Inc. ViewPoint™ CK System / Conductive Keratoplasty® (CK®) procedure was approved on April 11, 2002 under P010018 for the indication of the temporary reduction of spherical hyperopia in patients who have 0.75 to 3.25 D of cycloplegic spherical hyperopia, less than or equal to 0.75 D of refractive astigmatism (minus cylinder format), a cycloplegic spherical equivalent of 0.75 to 3.00 D, and are 40 years of age or greater with a documented stability of refraction for the prior 12 months, as demonstrated by a change of less than 0.50 D in spherical and cylindrical components of the manifest refraction. The magnitude of correction with this treatment diminishes over time, with some patients retaining some or all of their intended refractive correction.

The sponsor submitted this supplement to further expand the clinical indications. The updated clinical data to support this indication are provided in this summary. The pre-clinical test results were presented in the original PMA application. For more information on the data that supported the approved indication, the summary of safety and effectiveness data (SSED) for the original PMA should be referenced. Written requests for copies of the SSED can be obtained from Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857 under Docket #02M-0174 (P010018) or you may download the file from the internet site http://www.fda.gov/cdrh/pdf/p010018.html.

II. INDICATIONS FOR USE

The Viewpoint CK System is indicated for the temporary induction of myopia (-1.00 D to -2.00 D) to improve near vision in the non-dominant eye of presbyopic hyperopes or presbyopic emmetropes, via spherical hyperopic treatment of 1.00 to 2.25 D, in patients:

- 40 years of age or greater;
- with a documented stability of refraction for the prior 12 months, as demonstrated by a change of < 0.50D in spherical and cylindrical components of the manifest refraction;
- with ≤0.75 D of cycloplegic refractive cylinder; and
- with a successful preoperative trial of monovision or history of monovision wear (i.e., dominant eye corrected for distance vision and non-dominant eye corrected for near vision).

III. CONTRAINDICATIONS

The Refractec ViewPoint™ CK System / Conductive Keratoplasty® (CK®) procedure should not be used in:

- Patients who are pregnant or lactating.
- Patients with keratoconus or other ectatic diseases.
- Patients who have diabetes, diagnosed autoimmune disease, connective tissue disease, or clinically significant atopic syndrome.
- Patients who are being treated with chronic systemic corticosteroid or other immunosuppressive therapy that may affect wound healing, and any immunocompromised patients.
- Patients with implantable electrical devices (pacemakers, defibrillators, cochlear implants, etc).
- Patients with nystagmus or other condition that prevents a steady gaze, which is required during surgery.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the device labeling.

V. DEVICE DESCRIPTION

The ViewPoint™ CK System is an instrument designed to perform Conductive Keratoplasty® (CK®). CK® is an approved procedure for the temporary spherical treatment for patients with previously untreated hyperopia (farsightedness) between 0.75 and 3.00 diopters.

CK® can also be used for the temporary induction of myopia (-1.00 D to -2.00 D) in the non-dominant eye to improve near vision (monovision) in presbyopic hyperopes or presbyopic emmetropes. CK® is performed utilizing the ViewPoint™ CK System to create monovision.

Conductive Keratoplasty® utilizes low energy, delivered directly into the corneal stroma through a handpiece and Keratoplast™ Tip, to effect refractive change in the cornea. As a result of conducting a controlled amount of radiofrequency (RF) energy into the corneal stroma, the desired collagen shrinkage temperature is achieved. The peripheral application of this treatment, in a predetermined pattern, creates a band of tightening and results in a steepening of the central cornea. This steepening results in the desired refractive effect.

Overview of the ViewPoint™ CK System

The ViewPoint™ CK System used to perform the CK® procedure consists of the following components:

- Radiofrequency energy-generating console
- Reusable corneal marker
- Reusable lid speculum with cable and connector
- Reusable hand-held, pen-shaped handpiece with cable and connector
- Instrument holder
- Power cable
- Footpedal
- Disposable Keratoplast™ Tip
- Patient treatment card

Refractec submitted declarations that the ViewPoint™ CK System conforms to the following standards:

- ISO/EN 60601-1 Electrical Safety
- ISO/EN 60601-1-2 EMC
- ISO/EN 60601-2-2 Electrical Safety For RF
- ISO/EN 60601-1-4 Programmable Electrical Medical Systems
- ISO 10993 Biocompatibility
- ISO 10993-7 ETO Residuals
- ISO 11135 ETO Sterilization

ViewPoint™ CK System Console

A patient treatment card is inserted into the console to activate the system. The energy level is set at 60% power (0.6W) with a treatment time of 0.6 seconds. An AC powered, portable, low power, energy source provides regulated radiofrequency energy through the handpiece to the Keratoplast™ Tip.

Handpiece

The handpiece is a small hand-held, pen-shaped reusable Titanium instrument attached by a removable cable and connector to the console. The radiofrequency energy is delivered by means of the Keratoplast™ Tip, which attaches to the handpiece.

Keratoplast™ Tip

A sterile, disposable, stainless steel, Keratoplast™ Tip, 90 microns in diameter and 450 microns long, that delivers radiofrequency energy directly to the corneal stroma, is attached to the handpiece. The Keratoplast™ Tip has a proximal bend of 45° and a distal bend of 90° to allow access to the cornea over the patient's brow and nasal regions. A plastic stop at the very distal portion of the stainless steel tip assures correct depth of penetration. The Keratoplast™ Tip must not be used on fellow eyes or subsequent patients.

Lid Speculum

The lid speculum serves as the return (dispersive) electrode for the radiofrequency energy being delivered through the Keratoplast™ Tip. Three types of specula are offered: Barraquer, Cook, and Lancaster. The Barraquer is a small, malleable wire-speculum; the Cook is a small locking speculum; and the Lancaster is a large locking speculum. The Lancaster and Cook lid specula were not used in the clinical investigation of the device.

Footpedal

The footpedal attaches to the console and controls the release of radiofrequency energy.

Patient Treatment Card

A patient treatment card is inserted into the console to activate the system.

Safety Features

The ViewPoint™ CK System has numerous safety features to assure proper operation. The ViewPoint™ CK System includes safety checks at start-up and monitors output during treatment.

Software

The ViewPoint™ CK System software controls the user interface, and provides the user with system diagnostics and information codes in the event of a device anomaly. Additionally, the software saves all information codes on to the patient treatment card to assist in the diagnosis of technical issues.

VI. ALTERNATIVE PRACTICES OR PROCEDURES

Alternative methods of improving near vision include: reading glasses, bifocal eyeglasses, multifocal contact lenses, and monovision contact lens wear.

VII. MARKETING HISTORY

The ViewPoint™ CK System has been commercially distributed in 23 countries (Argentina, Australia, Belgium, Brazil, China, Finland, France, Germany, Greece, Hong Kong, Italy, Korea, Mexico, Netherlands, Paraguay, Spain, Saudi Arabia, South Africa, Switzerland, Taiwan, UAE, and the United Kingdom).

The ViewPoint™ CK System has not been withdrawn from any country or market for reasons of safety or effectiveness of the device.

VIII. POTENTIAL ADVERSE EVENTS OF THE DEVICE ON HEALTH

Potential adverse events associated with the CK® procedure include: decrease in BCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction at 6 months or later, IOP > 25 mmHg, secondary surgical intervention other than CK® treatment, late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BCVA, a corneal epithelial defect involving the treatment site, corneal edema, corneal microbial infection, corneal decompensation, corneal scar in the visual axis, intraocular infection, hypopyon, hyphema, onset of cataract unrelated to age/systemic disease/ trauma, retinal detachment, retinal vascular accidents.

Please refer to the complete listings of adverse events and complications observed during the clinical study, which are presented in the clinical study section.

IX. SUMMARY OF PRECLINICAL STUDIES

Please refer to the SSED of the original PMA P010018.

X. SUMMARY OF CLINICAL STUDIES

Refractec, Inc. conducted a clinical study of the ViewPoint™ CK System for the improvement of near vision at five U.S. clinical sites under the auspices of an Investigational Device Exemption (IDE) G980224. The data from this study served as the basis for the approval decision. Safety and effectiveness outcomes through 12 months post-treatment were evaluated for confirmation.

A. Objectives

The primary objective of the study was to evaluate the safety and effectiveness of the ViewPoint™ CK System used to improve near vision in presbyopic emmetropes and hyperopes with the Conductive Keratoplasty (CK®) procedure.

B. Study Design

This study was a prospective, multi-center clinical study where the primary control was the preoperative status of the treated eye.

1. Inclusion and Exclusion Criteria

Enrollment in the clinical study was limited to patients who:

- Required a presbyopic add of +1.00 to +2.00 D, with either a documented history of successful contact lens monovision or successful completion of contact lens monovision trial.
- Had +2.00 D to plano (+0.50 to -0.50 D) cycloplegic spherical equivalent, with $\leq$ 0.75 D refractive cycloplegic astigmatism (cylinder).
- Discontinued using hard or rigid gas permeable contact lenses for at least 3 weeks and discontinued using soft contact lenses for at least 2 weeks prior to the preoperative evaluation in the eye to be treated.
- Had an average peripheral pachymetry reading of at least 560 microns.
- For hard contact lens wearers – had 2 central keratometry readings and 2 manifest refractions taken at least one week apart, the last of which did not differ from the previous values by more than 0.50 D in either meridian; mires were regular in the eye to be treated.
- Had distance visual acuity correctable to at least 20/40 in both eyes and near visual acuity correctable to at least J3 in the non-dominant eye.
- Were at least 40 years of age.
- Were willing and able to return for scheduled follow-up examinations for 24 months after surgery.
- Provided written informed consent.

Patients with the following conditions were excluded from the study:

- Spherical equivalent manifest refraction and spherical equivalent cycloplegic refraction with a difference of more than 0.50 D.
- Previous strabismus surgery, or who would have been likely to develop strabismus following the CK® procedure.

- Anterior segment pathology, including cataracts (in the operative eye).
- Any corneal abnormality or uncontrolled eyelid disease (in the operative eye).
- Ophthalmoscopic signs of progressive or unstable refractive error (in the operative eye).
- Distorted or unclear corneal mires.
- Blind in the fellow eye.
- Previous intraocular or corneal surgery.
- History of herpes zoster or herpes simplex keratitis.
- History of steroid-responsive rise in IOP, glaucoma, or preoperative IOP > 21 mmHg.
- At risk for angle closure or with a potentially occludable angle.
- Diabetes, diagnosed autoimmune disease, connective tissue disease, or clinically significant atopic syndrome.
- Chronic systemic corticosteroid or other immunosuppressive therapy, and any immunocompromised patients.
- Using ophthalmic medication(s) other than artificial tears for treatment of any ocular pathology.
- Using systemic medications with significant ocular side effects.
- History of keloid formation.
- Intractable keratoconjunctivitis sicca.
- Pregnant, planning to be pregnant, or lactating during the course of the study.
- Known sensitivity to planned study concomitant medications.
- Participating in any other ophthalmic drug or device clinical trial during the time of this clinical investigation.

2. Study Endpoints

The following primary study parameters were evaluated in the determination of safety and effectiveness of the ViewPoint™ CK System for hyperopic and emmetropic eyes treated for near.

Primary Safety Parameter:

- Preservation of best corrected distance visual acuity: less than 5% of eyes were to lose more than 2 lines of best corrected distance visual acuity at the postoperative interval at which stability has been established.

Primary Effectiveness Parameter:

- Predictability: 75% of eyes were to have a manifest refraction spherical equivalent within ± 1.00 D of the attempted correction at the postoperative interval at which stability has been established.

The following secondary study parameters were evaluated in the determination of safety and effectiveness of the ViewPoint™ CK System for hyperopic and emmetropic eyes treated for near.

Secondary Safety Parameters:

- Preservation of best corrected near visual acuity: less than 5% of eyes were to lose more than 2 lines of best corrected near visual acuity at the postoperative interval at which stability has been established.
- Preservation of best corrected distance and near visual acuity: less than 1% of eyes with preoperative BCVA of 20/20 were to have distance and near visual acuity worse than 20/40 BCVA at the postoperative interval at which stability has been established.
- Mean extent of induced manifest refractive astigmatism: less than 5% of eyes were to have postoperative manifest refractive astigmatism that increased from baseline by greater than 2.00 D at the postoperative interval at which stability has been established.
- Results of slit lamp examination: less than 1% of eyes were to have clinically significant haze, defined as a decrease in BCVA of > 2 lines not due to irregular astigmatism, at the postoperative interval at which stability has been established.
- Cumulative incidence of adverse events: adverse events were to occur in less than 5% of eyes and any single adverse event should occur in less than 1% of eyes.

Secondary Effectiveness Parameters:

- Predictability: 50% of eyes were to have a manifest refraction spherical equivalent within $\pm$ 0.50 D of the attempted correction at the postoperative interval at which stability has been established.
- Stability (absence of change in refractive outcome over time): 95% of eyes were to have a change of $\leq$ 1.00 D in manifest refraction spherical equivalent between two refractions performed at least three months apart.
- Improvement in distance uncorrected visual acuity: 85% of eyes who had 20/20 or better spectacle-corrected visual acuity preoperatively, were to have uncorrected visual acuity of 20/40 or better at the postoperative interval at which stability has been established. For those eyes which had spectacle-corrected visual acuity of worse than 20/20 but at least 20/40 preoperatively, 75% were to have uncorrected visual acuity of 20/40 or better at the postoperative interval at which stability has been established.
- Improvement in near uncorrected visual acuity: 75% of eyes that had a full correction were to have uncorrected near visual acuity of J3 or better.
- Subject satisfaction as measured by subjective questionnaires.

C. Study Plan and Subject Assessments

1. Study Plan

All subjects were expected to return for follow-up examinations at 1 day, 7 days, and 1, 3, 6, 9, 12, and 24 months post-treatment. CK retreatments were allowed per the study protocol for up to a maximum of 32 spots.

2. Subject Assessments and Efficacy Criteria

- Monocular and binocular near visual acuity, uncorrected and best spectacle-corrected
- Monocular and binocular distance visual acuity, uncorrected and best spectacle-corrected
- Manifest refraction
- Cycloplegic refraction
- Pachymetry (preoperative)
- Intraocular pressure
- Slit lamp examination
- Mesopic and photopic contrast sensitivity, with and without glare (subgroup)
- Computerized corneal topography (postoperatively in eyes with anomalous refractive outcomes)
- Central keratometry
- Subject self-evaluation/questionnaire
- Subject spectacle dependence evaluation/questionnaire

D. Study Period and Investigational Sites

Subjects were treated between May 15, 2001 and January 7, 2003 at 5 investigational sites. The database for this PMA supplement cohort reflects data collected through July 21, 2003 and includes 188 eyes of 150 subjects: 150 primary eyes treated for near and 38 fellow eyes treated for distance.

E. Demographic Data

As presented in Table 1 below, of the 150 subjects enrolled, 61% were female and 39% were male. The mean age for all enrolled subjects was 52.9 years, with a range from 43.7 to 70.8 years. The study population consisted primarily of Caucasians (96%). The mean intended correction for near eyes was 2.03 D.

Table 1
Demographics

		Near Eyes 150 Eyes of 150 Subjects	Distance Eyes 38 Eyes of 38 Subjects	All Eyes 188 Eyes of 150 Subjects
Gender	Male	58 39%	13 34%	58 39%
	Female	92 61%	25 66%	92 61%
Race	Caucasian	144 96%	37 97%	144 96%
	Black	1 1%	0 0%	1 1%
	Asian	1 1%	1 3%	1 1%
	Other	4 3%	0 0%	4 3%
Eye	Left	83 55%	16 42%	99 53%
	Right	67 45%	22 58%	89 47%
Age (yrs)	N	150	38	150
	Mean	52.9	54.1	52.9
	Standard Deviation	4.80	4.77	4.80
	Median	52.0	53.8	52.0
	Range	43.7,70.8	43.7,61.3	43.7,70.8
Range of Intended Correction	N	150	38	
	Mean	2.03	1.23	
	Standard Deviation	0.625	0.367	
	Median	2.00	1.25	
	Range	0.75,3.00	0.75,2.00	
Range of Target	N	150	38	
	Mean	-1.47	0.00	
	Standard Deviation	0.356	0.000	
	Median	-1.25	0.00	
	Range	-2.25,-1.00	0.00,0.00	

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F. Data Analysis and Results

1. Pre-Treatment Characteristics

Table 2 presents a summary of the pre-treatment refraction for near and distance eyes. The treatment goal for near treated eyes was myopia and for distance treated eyes the treatment goal was emmetropia.

Table 2
Preoperative Refractive Parameters

		Near Eyes		Distance Eyes	
Spherical Equivalent (MRSE) *	-0.50 to -0.125 D	19	13%	0	0%
	0.0-0.99 D	99	66%	12	32%
	1.0-2.00 D	32	21%	26	68%
	Total	150	100%	38	100%
Cylinder (manifest)	0.00 D	53	35%	10	26%
	-0.25 D	27	18%	7	18%
	-0.50 D	45	30%	18	47%
	-0.75 D	25	17%	3	8%
	-1.00 D	0	0%	0	0%
	Total	150	100%	38	100%
Spherical Equivalent (CRSE) *	-0.50 to -0.125 D	17	11%	0	0%
	0.0-0.99 D	92	61%	9	24%
	1.0-2.00 D	41	27%	29	76%
	Total	150	100%	38	100%
Cylinder (cycloplegic)	0.00 D	52	35%	11	29%
	-0.25 D	30	20%	7	18%
	-0.50 D	41	27%	15	39%
	-0.75 D	27	18%	4	11%
	-1.00 D	0	0%	1	3%
	Total	150	100%	38	100%

* Per study inclusion criteria, emmetropes desiring near correction were enrolled with plano (defined as -0.50 to +0.50 D) One ineligible subject was enrolled with -0.75 D preoperative CRSE.

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2. Subject Accountability

Of the 150 near eyes enrolled in the study, follow-up data through 6 months postoperative are available for 146 eyes (97%), as shown in Table 3. Of the remaining eyes at 6 months, one (<1%) was discontinued from the study due to retreatment with surface ablation, one (<1%) was discontinued for CK retreatment and re-enrolled and four (3%) missed their scheduled 6 month postoperative visit.

Table 3
Accountability
Eyes Treated for Near

	Month 1		Month 3		Month 6		Month 9		Month 12	
Available for Analysis	145/150	97%	148/150	99%	146/150	97%	94/150	63%	77/150	51%
Discontinued*	0/150	0%	0/150	0%	2/150	1%	4/150	3%	9/150	6%
Missed Visit	5/150	3%	2/150	1%	4/150	3%	3/150	2%	3/150	2%
Not yet eligible for interval	0/150	0%	0/150	0%	0/150	0%	53/150	35%	70/150	47%
Lost to Follow-up	0/150	0%	0/150	0%	0/150	0%	0/150	0%	1/150	1%
Accountability	145/150	97%	148/150	99%	146/150	97%	94/97	97%	77/80	96%

* 1 eye discontinued due to inability of patient to continue in study; 1 eye discontinued due to an adverse event (multiple sclerosis); 1 eye discontinued for retreatment with PRK; 12 eyes discontinued for CK retreatment as per study protocol. See Table 16.2.

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3. Summary of Key Effectiveness Variables

Tables 4 demonstrates that the key effectiveness outcomes at 6 months postoperative meet or exceed the outcomes recommended in the October 10, 1996 *FDA Guidance for Refractive Surgery Lasers*. The clinical trial included eyes within a treatment range of +0.75 to 3.00 D. The final approved indication limited the treatment range to +1.00 to 2.25 D. The other eyes treated reported adequate safety but demonstrated an efficacy, which was significantly below that for the approved indication.

Table 4
Summary of Key Efficacy Variables
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 1		Month 3		Month 6		Month 9		Month 12	
Efficacy Variables -- Eyes Treated for Near (Full Correction)*										
UCVA-N J1+ or better	22/78	28%	20/81	25%	19/81	23%	16/64	25%	7/53	13%
UCVA-N J1 or better	46/78	59%	44/81	54%	41/81	51%	31/64	48%	20/53	38%
UCVA-N J2 or better	64/78	82%	62/81	77%	59/81	73%	48/64	75%	37/53	70%
UCVA-N J3 or better	71/78	91%	71/81	88%	67/81	83%	54/64	84%	43/53	81%
UCVA-N J5 or better	76/78	97%	79/81	98%	76/81	94%	59/64	92%	52/53	98%
UCVA-N J7 or better	78/78	100%	81/81	100%	79/81	98%	62/64	97%	53/53	100%
Efficacy Variables -- Eyes Treated for Near*										
MRSE ≤ 0.5 D from Target	55/88	63%	60/91	66%	59/91	65%	50/73	68%	43/62	69%
MRSE ≤ 1.0 D from Target	79/88	90%	82/91	90%	83/91	91%	66/73	90%	58/62	94%
MRSE ≤ 2.0 D from Target	88/88	100%	91/91	100%	91/91	100%	73/73	100%	62/62	100%

* Efficacy analyses exclude 3 eyes with a target near correction of > -2.00 D, the maximum allowed in the protocol.

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Table 5a
Summary of Key Efficacy Variables at Month 6, Stratified by Treatment Spots Applied
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	16 Spots 1.00 - 1.63 D		24 Spots 1.75 - 2.25 D	
Efficacy Variables -- Eyes Treated for Near with Full Correction*				
UCVA-N J1+ or better	9/36	25%	10/44	23%
UCVA-N J1 or better	14/36	39%	26/44	59%
UCVA-N J2 or better	26/36	72%	32/44	73%
UCVA-N J3 or better	30/36	83%	36/44	82%
UCVA-N J5 or better	32/36	89%	43/44	98%
UCVA-N J7 or better	34/36	94%	44/44	100%
Efficacy Variables -- Eyes Treated for Near*				
MRSE ≤ 0.5 D from Target	28/42	67%	31/48	65%
MRSE ≤ 1.0 D from Target	38/42	90%	44/48	92%
MRSE ≤ 2.0 D from Target	42/42	100%	48/48	100%

* Efficacy analyses exclude 3 eyes with a target near correction of > -2.00 D, the maximum allowed in the protocol.

Note: Table excludes 1 eye treated intraoperatively with additional treatment spots for management of induced cylinder.

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Table 5b
Summary of Key Efficacy Variables at Month 12, Stratified by Treatment Spots Applied
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	16 Spots 1.00 - 1.63 D		24 Spots 1.75 - 2.25 D	
Efficacy Variables -- Eyes Treated for Near with Full Correction*				
UCVA-N J1+ or better	6/28	21%	1/25	4%
UCVA-N J1 or better	13/28	46%	7/25	28%
UCVA-N J2 or better	22/28	79%	15/25	60%
UCVA-N J3 or better	25/28	89%	18/25	72%
UCVA-N J5 or better	28/28	100%	24/25	96%
UCVA-N J7 or better	28/28	100%	25/25	100%
Efficacy Variables -- Eyes Treated for Near*				
MRSE ≤ 0.5 D from Target	28/34	82%	15/28	54%
MRSE ≤ 1.0 D from Target	33/34	97%	25/28	89%
MRSE ≤ 2.0 D from Target	34/34	100%	28/28	100%

* Efficacy analyses exclude 3 eyes with a target near correction of > -2.00 D, the maximum allowed in the protocol.

Note: Table excludes 1 eye treated intraoperatively for induced cylinder.

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Table 5c
Eyes Undercorrected by > 1.00 D,
Stratified by Treatment Spots Applied
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	16 Spots 1.00 – 1.63 D		24 Spots 1.75 – 2.25 D	
6 Months	4/42	10%	4/49	8%
12 Months	1/34	3%	3/28	11%

Table 5d
Proportion of Eyes with Near UCVA J3 (20/40) or Better at 6 Months,
Stratified by Age and Treatment Spots Applied
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	≤ 50 years		50 to < 55 years		≥ 55 years		All Eyes	
16 spots 1.00 – 1.63 D	11/14	79%	11/12	92%	8/10	80%	**30/36**	**83%**
24 spots 1.75 – 2.25 D	14/14	100%	16/22	73%	7/9	78%	**37/45**	**82%**
All Eyes	**25/28**	**89%**	**27/34**	**79%**	**15/19**	**79%**		

The improvement in near vision is accomplished through the application of CK to the non-dominant eye to achieve a myopic endpoint (-1.00 to -2.00 D). Therefore, it is important to assess the impact of intentional anisometropia on binocular vision. Binocular cumulative uncorrected visual acuity at near for eyes treated for a full correction at near is shown in Table 6.

Table 6
Binocular Cumulative Uncorrected Visual Acuity - Near
All Subjects Treated for Near with Intended Correction of 1.00 to 2.25 D (Full Correction)

	Preop		Month 1		Month 3		Month 6		Month 9		Month 12	
UCVA-N J1+ or better	0/81	0%	29/78	37%	25/81	31%	23/81	28%	18/64	28%	12/53	23%
UCVA-N J1 or better	1/81	1%	52/78	67%	54/81	67%	45/81	56%	38/64	59%	25/53	47%
UCVA-N J2 or better	6/81	7%	66/78	85%	63/81	78%	66/81	81%	54/64	84%	41/53	77%
UCVA-N J3 or better	12/81	15%	73/78	94%	74/81	91%	73/81	90%	58/64	91%	47/53	89%
UCVA-N J5 or better	30/81	37%	77/78	99%	80/81	99%	78/81	96%	61/64	95%	52/53	98%
UCVA-N J7 or better	51/81	63%	78/78	100%	81/81	100%	80/81	99%	63/64	98%	53/53	100%
UCVA-N J10 or better	69/81	85%	78/78	100%	81/81	100%	80/81	99%	64/64	100%	53/53	100%
UCVA-N J16 or better	80/81	99%	78/78	100%	81/81	100%	81/81	100%	64/64	100%	53/53	100%
Not reported	0/81	0%	0/78	0%	0/81	0%	0/81	0%	0/64	0%	0/53	0%
Total	81/81	100%	78/78	100%	81/81	100%	81/81	100%	64/64	100%	53/53	100%

Note: Efficacy analyses exclude 3 eyes with a target near correction of > -2.00 D, the maximum allowed in the protocol.

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Binocular cumulative uncorrected visual acuity at distance is shown in Table 7.

Table 7
Binocular Cumulative Uncorrected Visual Acuity - Distance
All Subjects Treated for Near with Intended Correction of 1.00 to 2.25 D

	Preop		Month 1		Month 3		Month 6		Month 9		Month 12	
UCVA-D 20/20 or better	84/91	92%	85/87	98%	88/91	97%	86/91	95%	72/73	99%	60/62	97%
UCVA-D 20/25 or better	89/91	98%	87/87	100%	90/91	99%	91/91	100%	73/73	100%	61/62	98%
UCVA-D 20/32 or better	90/91	99%	87/87	100%	91/91	100%	91/91	100%	73/73	100%	62/62	100%
UCVA-D 20/40 or better	91/91	100%	87/87	100%	91/91	100%	91/91	100%	73/73	100%	62/62	100%
UCVA-D 20/80 or better	91/91	100%	87/87	100%	91/91	100%	91/91	100%	73/73	100%	62/62	100%
UCVA-D 20/200 or better	91/91	100%	87/87	100%	91/91	100%	91/91	100%	73/73	100%	62/62	100%
Not reported	0/91	0%	1/88	1%	0/91	0%	0/91	0%	0/73	0%	0/62	0%
Total	91/91	100%	87/87	100%	91/91	100%	91/91	100%	73/73	100%	62/62	100%

Note: Efficacy analyses exclude 3 eyes with a target near correction of > -2.00 D, the maximum allowed in the protocol.

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To ensure that study subjects did not experience an improvement in uncorrected near vision with a concurrent compromise in uncorrected distance acuity, the combination of binocular uncorrected near and distance visual acuity is shown in Table 8.

Table 8
Combined Binocular Uncorrected Visual Acuity Distance and Near
All Subjects Treated for Near with Intended Correction of 1.00 to 2.25 D (Full Correction)

	Preop		Month 1		Month 3		Month 6		Month 9		Month 12	
20/20 or better and J1 or better	1/81	1%	50/77	65%	51/81	63%	41/81	51%	38/64	59%	24/53	45%
20/25 or better and J2 or better	6/81	7%	65/77	84%	62/81	77%	66/81	81%	54/64	84%	41/53	77%
20/32 or better and J3 or better	12/81	15%	72/77	94%	74/81	91%	73/81	90%	58/64	91%	47/53	89%
20/40 or better and J3 or better	12/81	15%	72/77	94%	74/81	91%	73/81	90%	58/64	91%	47/53	89%
Not reported	0/81	0%	1/78	1%	0/81	0%	0/81	0%	0/64	0%	0/53	0%
Total	81/81	100%	77/77	100%	81/81	100%	81/81	100%	64/64	100%	53/53	100%

Note: Efficacy analyses exclude 3 eyes with a target near correction of > -2.00 D, the maximum allowed in the protocol.

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a. Factors Associated with Outcomes

Statistical modeling performed on the data generated in the CK® clinical study found no effect of age, race, sex or clinical site on outcomes.

b. Subject Satisfaction

Subjects were asked to rate their quality of vision compared to before the Conductive Keratoplasty® (CK®) procedure. Table 9 shows the percentage of subjects that rated each condition as improvement that was "extreme," "marked," "moderate," "slight," or "no improvement".

Table 9
Quality of Vision
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 1		Month 3		Month 6		Month 9		Month 12	
Extreme Improvement	32/89	36%	40/92	43%	40/93	43%	28/74	38%	24/62	39%
Marked Improvement	36/89	40%	32/92	35%	30/93	32%	23/74	31%	26/62	42%
Moderate Improvement	13/89	15%	15/92	16%	13/93	14%	17/74	23%	9/62	15%
Slight Improvement	6/89	7%	4/92	4%	7/93	8%	3/74	4%	2/62	3%
No Improvement	2/89	2%	1/92	1%	3/93	3%	3/74	4%	1/62	2%
Not Reported	1/90	1%	1/93	1%	0/93	0%	0/74	0%	1/63	2%
Total	89/89	100%	92/92	100%	93/93	100%	74/74	100%	62/62	100%

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Overall subject satisfaction was assessed on a subject survey at 1, 3, 6, 9, and 12 months post-treatment using a 5-point grading scale from "very satisfied" to "very dissatisfied" (Table 10).

Table 10
Patient Satisfaction
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 1		Month 3		Month 6		Month 9		Month 12	
Very Satisfied	49/90	54%	54/92	59%	48/93	52%	38/74	51%	35/62	56%
Satisfied	29/90	32%	25/92	27%	26/93	28%	21/74	28%	17/62	27%
Neutral	7/90	8%	11/92	12%	16/93	17%	12/74	16%	7/62	11%
Dissatisfied	5/90	6%	2/92	2%	3/93	3%	3/74	4%	3/62	5%
Very Dissatisfied	0/90	0%	0/92	0%	0/93	0%	0/74	0%	0/62	0%
Not Reported	0/90	0%	1/93	1%	0/93	0%	0/74	0%	1/63	2%
Total	90/90	100%	92/92	100%	93/93	100%	74/74	100%	62/62	100%

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Table 11
Quality of Depth Perception
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Preop*		Month 1		Month 3		Month 6		Month 9		Month 12	
Depth Perception*												
Excellent	15/81	19%	11/90	12%	25/91	27%	22/93	24%	15/73	21%	12/61	20%
Very Good	30/81	37%	34/90	38%	26/91	29%	39/93	42%	28/73	38%	24/61	39%
Good	31/81	38%	38/90	42%	34/91	37%	24/93	26%	25/73	34%	21/61	34%
Fair	4/81	5%	7/90	8%	6/91	7%	6/93	6%	5/73	7%	4/61	7%
Poor	1/81	1%	0/90	0%	0/91	0%	2/93	2%	0/73	0%	0/61	0%
Not Reported	13/94	14%	0/90	0%	2/93	2%	0/93	0%	1/74	1%	2/63	3%
Total	81/81	100%	90/90	100%	91/91	100%	93/93	100%	73/73	100%	61/61	100%

* Preoperative depth perception was assessed wearing monovision contact lenses rather than assessing depth perception with both eyes corrected for distance (non-monovision baseline).

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The questionnaire used during the study asked a single question regarding use of spectacles or contact lenses for near vision and distance vision, the results of which are shown below in Tables 12 and 13.

Table 12
Spectacle Dependence for Near Vision
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 1		Month 3		Month 6		Month 9		Month 12	
Do you wear spectacles or contact lenses for near vision in your treated eye?	28/90	31%	27/93	29%	36/93	39%	32/74	43%	33/63	52%
All near activities	3/90	3%	4/93	4%	14/93	15%	12/74	16%	8/63	13%
Working on computer	13/90	14%	10/93	11%	14/93	15%	16/74	22%	10/63	16%
Reading	28/90	31%	26/93	28%	34/93	37%	30/74	41%	33/63	52%

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Table 13
Spectacle Dependence for Distance Vision
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 1		Month 3		Month 6		Month 9		Month 12	
Do you wear spectacles or contact lenses for distance vision in your treated eye?	0/90	0%	2/93	2%	2/93	2%	3/74	4%	2/63	3%
Whenever driving	0/90	0%	0/93	0%	1/93	1%	2/74	3%	1/63	2%
Night driving only	0/90	0%	2/93	2%	2/93	2%	1/74	1%	1/63	2%
Watching TV or movies	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Sporting events/activities only	0/90	0%	0/93	0%	0/93	0%	0/74	0%	1/63	2%
All distance activities (full time)	0/90	0%	0/93	0%	0/93	0%	0/74	0%	1/63	2%

RCS-011-PRS Source: /refractec/pres sas/weard_tab.sas Date Generated: 18FEB04 Data Lock: 21JUL2003

4. Change in Manifest Refraction Over Time

Table 14a
Stability of Manifest Refraction through Month 12 (Eyes with Consecutive Visits)
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
Change in MRSE ≤ 0.50 D	70/88 80%	78/91 86%	72/73 99%	59/62 95%
Change in MRSE ≤ 0.75 D	80/88 91%	86/91 95%	72/73 99%	60/62 97%
Change in MRSE ≤ 1.00 D	83/88 94%	91/91 100%	73/73 100%	61/62 98%
Change in MRSE/Month (Paired Differences in D)				
Mean	0.06	0.04	0.04	0.03
95% Confidence Interval	0.00,0.12	0.02,0.06	0.02,0.06	0.01,0.05
Standard Deviation	0.241	0.125	0.081	0.098
Change in MRSE (Paired Differences in D)				
Mean	0.12	0.13	0.11	0.10
95% Confidence Interval	0.02,0.22	0.05,0.21	0.05,0.17	0.02,0.18
Standard Deviation	0.482	0.375	0.243	0.293

Note: Efficacy analyses exclude 3 eyes with a target near correction of > -2.00 D, the maximum allowed in the protocol.

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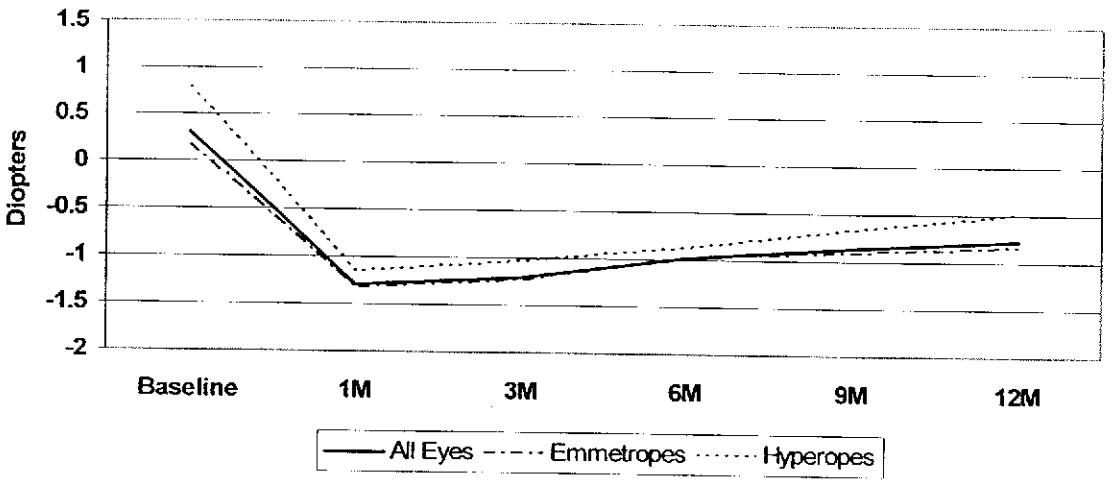
Table 14b
Mean Difference in MRSE*
Stratified by Spot Pattern (Consecutive Visits)
All Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

		Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months	Between 9 and 12 Months
16 Spots 1.00 – 1.63 D	N	40	42	40	34
	Mean	0.05	0.06	0.01	0.02
	95% CI	-0.01, 0.11	0.02, 0.10	-0.01, 0.03	0.00, 0.04
	SD	0.191	0.111	0.075	0.068
24 Spots 1.75 – 2.25 D	N	47	48	33	28
	Mean	0.06	0.02	0.06	0.06
	95% CI	-0.02, 0.14	-0.02, 0.06	0.04, 0.08	0.02, 0.10
	SD	0.270	0.136	0.080	0.122

* The duration of the initial refractive effect is not known.

Mean MRSE Over Time
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D



5. Summary of Key Safety Variables

Table 15 demonstrates that the key safety outcomes meet or exceed the outcomes recommended in the October 10, 1996 *FDA Guidance for Refractive Surgery Lasers.*

Table 15
Summary of Key Safety Variables
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 1		Month 3		Month 6		Month 9		Month 12	
Safety Variables -- Eyes Treated for Near										
Loss of > 2 lines BCVA-D	2/90	2%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Loss of ≥ 2 lines BCVA-D	3/90	3%	1/93	1%	2/93	2%	0/74	0%	0/63	0%
BCVA-D worse than 20/40	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Increase > 2 D cylinder	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Preop BCVA-D ≤ 20/20 to >20/25	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Loss of > 2 lines BCVA-N	0/89	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Loss of ≥ 2 lines BCVA-N	0/89	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
BCVA-N worse than J3	0/89	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%

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Table 16a
Summary of Key Safety Variables at Month 6, Stratified by Treatment Spots Applied Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	16 Spots 1.00 - 1.63 D		24 Spots 1.75 - 2.25 D	
Safety Variables – Eyes Treated for Near				
Loss of > 2 lines BCVA-D	0/42	0%	0/50	0%
Loss of ≥ 2 lines BCVA-D	0/42	0%	2/50	4%
BCVA-D worse than 20/40	0/42	0%	0/50	0%
Increase > 2 D cylinder	0/42	0%	0/50	0%
Preop BCVA-D ≤ 20/20 to >20/25	0/42	0%	0/50	0%
Loss of > 2 lines BCVA-N	0/42	0%	0/50	0%
Loss of ≥ 2 lines BCVA-N	0/42	0%	0/50	0%
BCVA-N worse than J3	0/42	0%	0/50	0%

Note: Table excludes 1 eye treated intraoperatively with additional treatment spots for management of induced cylinder.

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Table 16b
Summary of Key Safety Variables at Month 12, Stratified by Treatment Spots Applied Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	16 Spots 1.00 - 1.63 D		24 Spots 1.75 - 2.25 D	
Safety Variables -- Eyes Treated for Near				
Loss of > 2 lines BCVA-D	0/34	0%	0/29	0%
Loss of ≥ 2 lines BCVA-D	0/34	0%	0/29	0%
BCVA-D worse than 20/40	0/34	0%	0/29	0%
Increase > 2 D cylinder	0/34	0%	0/29	0%
Preop BCVA-D ≤ 20/20 to >20/25	0/34	0%	0/29	0%
Loss of > 2 lines BCVA-N	0/34	0%	0/29	0%
Loss of ≥ 2 lines BCVA-N	0/34	0%	0/29	0%
BCVA-N worse than J3	0/34	0%	0/29	0%

Note: Table excludes 1 eye treated intraoperatively for induced cylinder.

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Table 17 presents a summary of the adverse events reported in the clinical study of the ViewPoint™ CK System for the improvement of near vision.

Table 17
Adverse Event Summary
Eyes Treated for Near

	Month 1*		Month 3		Month 6		Month 9		Month 12	
Late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BSCVA	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Decr. in BSCVA of > 10 letters not due to irreg. astig. as shown by hard contact lens refr., at 6 mo	0/150	0%	0/148	0%	1/146	1%	0/94	0%	0/77	0%
Any corneal epithelial defect involving the keratectomy site at 1 month or later	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Corneal infiltrate or ulcer	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Corneal edema at 1 month or later	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Corneal perforation	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Corneal microbial infection	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Corneal decompensation	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Corneal scar in visual axis	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Uncontrolled IOP with increase of > 5 mm Hg above baseline and any reading above 25 mm Hg	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
IOP >25 mm Hg	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Intraocular infection	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Hypopyon	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Hyphema	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Onset of cataract unrelated to age, systemic disease, or trauma	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Retinal detachment	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Retinal vascular accidents	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Secondary surgical intervention other than CK treatment	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Death	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%
Other	1/150	1%	0/148	0%	0/146	0%	1/94	1%	1/77	1%
Not reported	0/150	0%	0/148	0%	0/146	0%	0/94	0%	0/77	0%

* Includes adverse events reported from 1 day through 1 month postop.

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The following adverse event was reported as "Other" at one week at a rate of less than 1%:

- Mild iritis

During the first week following surgery, patients may experience: pain discomfort, a feeling of something in the eye (lasting from one up to three days after surgery), mild light sensitivity, and swelling of the cornea.

Table 18 presents a summary of the complications reported in the clinical study.

Table 18
Complication Summary
Eyes Treated for Near

	Month 1		Month 3		Month 6		Month 9		Month 12	
Peripheral corneal epithelial defect at one month	0/145	0%	0/149	0%	0/146	0%	0/94	0%	0/77	0%
Corneal edema between one week and one month after	0/145	0%	0/149	0%	0/146	0%	0/94	0%	0/77	0%
Recurrent corneal erosion at one month or later	0/145	0%	0/149	0%	0/146	0%	0/94	0%	0/77	0%
Double/ghost images in the operative eye	2/145	1%	2/149	1%	1/146	1%	0/94	0%	0/77	0%
Foreign body sensation at one month or later	1/145	1%	0/149	0%	1/146	1%	1/94	1%	1/77	1%
Pain at one month or later	0/145	0%	0/149	0%	0/146	0%	0/94	0%	0/77	0%
Other	2/145	1%	2/149	1%	0/146	0%	0/94	0%	0/77	0%
Not reported	0/145	0%	0/149	0%	0/146	0%	0/94	0%	0/77	0%

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In the clinical study of the ViewPoint™ CK System for the improvement of near vision, the following complication was reported as "Other" on the day of surgery at a rate of <1%:

- Treatment interruption (new tip needed after the 20th spot was applied due to bent tip)

Each of the following complications were reported as "Other" at the one week visit at a rate of <1%:

- Allergic conjunctivitis
- Blepharitis

The following complications were not reported in the clinical study, but could potentially occur following CK® procedure: peripheral corneal epithelial defect; corneal edema.

Table 19 below shows the absolute change in refractive cylinder for eyes treated for near.

Table 19
Absolute Change in Refractive Cylinder
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

Astigmatism	Month 1		Month 3		Month 6		Month 9		Month 12	
Increase >2.00 D	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Increase 2.00 D	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Increase 1.75 D	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Increase 1.50 D	5/90	6%	1/93	1%	0/93	0%	0/74	0%	0/63	0%
Increase 1.25 D	6/90	7%	8/93	9%	6/93	6%	2/74	3%	1/63	2%
Increase 1.00 D	15/90	17%	7/93	8%	3/93	3%	2/74	3%	4/63	6%
No Change (± 0.75 D)	64/90	71%	77/93	83%	84/93	90%	70/74	95%	58/63	92%
Decrease 1.00 D	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Decrease >1.00 D	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Not Reported	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Total	90/90	100%	93/93	100%	93/93	100%	74/74	100%	63/63	100%

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Table 20 presents a comparison of eyes with ≥ 1.00 D induced cylinder and eyes with <1.00 D induced cylinder.

Table 20
Comparison of Eyes with ≥ 1.00 D of Induced Cylinder and Eyes with < 1.00 D Induced Cylinder
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	< 1.00 D Induced Cylinder			≥ 1.00 D Induced Cylinder		
	Month 6	Month 9	Month 12	Month 6	Month 9	Month 12
Loss of > 2 lines BCVA-N	0/84 0%	0/70 0%	0/58 0%	0/9 0%	0/4 0%	0/5 0%
Loss of 2 lines BCVA-N	0/84 0%	0/70 0%	0/58 0%	0/9 0%	0/4 0%	0/5 0%
Loss of 1 line BCVA-N	3/84 4%	1/70 1%	0/58 0%	0/9 0%	0/4 0%	0/5 0%
No Change	67/84 80%	59/70 84%	49/58 84%	5/9 56%	3/4 75%	5/5 100%
Increase of 1 line BCVA-N	13/84 15%	9/70 13%	9/58 16%	3/9 33%	1/4 25%	0/5 0%
Increase of 2 lines BCVA-N	1/84 1%	1/70 1%	0/58 0%	1/9 11%	0/4 0%	0/5 0%
Increase of > 2 lines BCVA-N	0/84 0%	0/70 0%	0/58 0%	0/9 0%	0/4 0%	0/5 0%
UCVA-N J1 or better	42/84 50%	33/70 47%	20/58 34%	4/9 44%	1/4 25%	2/5 40%
UCVA-N J2 or better	58/84 69%	51/70 73%	39/58 67%	8/9 89%	3/4 75%	3/5 60%
UCVA-N J3 or better	66/84 79%	57/70 81%	45/58 78%	9/9 100%	4/4 100%	4/5 80%
UCVA-N J5 or better	77/84 92%	63/70 90%	54/58 93%	9/9 100%	4/4 100%	5/5 100%
UCVA-N J7 or better	81/84 96%	67/70 96%	56/58 97%	9/9 100%	4/4 100%	5/5 100%
UCVA-N						
N	84	70	58	9	4	5
Mean	2.44	2.51	2.74	1.59	1.92	2.40
95% Confidence Interval	1.95,2.93	1.88,3.14	2.07,3.41	1.08,2.10	0.98,2.86	0.93,3.87
Standard Deviation	2.298	2.719	2.619	0.794	0.956	1.673
Median	1.50	2.00	2.00	2.00	2.00	2.00
Range	0.67,10.00	0.67,16.00	0.67,16.00	0.67,3.00	0.67,3.00	1.00,5.00

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Table 21 below shows the absolute shift in cylinder axis.

Table 21
Absolute Shift in Axis
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

Induced Shift	Month 6			Month 9			Month 12		
	n/N	%	95% CI	n/N	%	95% CI	n/N	%	95% CI
0°	20/93	22%	0.137-0.312	17/74	23%	0.140-0.342	16/63	0%	0.153-0.379
1° to 5°	7/93	8%	0.031-0.149	9/74	12%	0.057-0.218	7/63	50%	0.046-0.216
6° to 10°	8/93	9%	0.038-0.162	5/74	7%	0.022-0.151	7/63	0%	0.046-0.216
11° to 15°	11/93	12%	0.061-0.202	5/74	7%	0.022-0.151	3/63	0%	0.010-0.133
16° to 20°	2/93	2%	0.003-0.076	3/74	4%	0.008-0.114	4/63	0%	0.018-0.155
21° to 25°	4/93	4%	0.012-0.106	1/74	1%	0.000-0.073	4/63	0%	0.018-0.155
26° to 30°	1/93	1%	0.000-0.058	2/74	3%	0.003-0.094	1/63	50%	0.000-0.085
31° to 35°	6/93	6%	0.024-0.135	3/74	4%	0.008-0.114	0/63	0%	0.000-0.057
36° to 40°	3/93	3%	0.007-0.091	5/74	7%	0.022-0.151	2/63	0%	0.004-0.110
41° to 45°	3/93	3%	0.007-0.091	1/74	1%	0.000-0.073	2/63	0%	0.004-0.110
46° to 50°	2/93	2%	0.003-0.076	4/74	5%	0.015-0.133	3/63	0%	0.010-0.133
51° to 55°	2/93	2%	0.003-0.076	2/74	3%	0.003-0.094	1/63	0%	0.000-0.085
56° to 60°	5/93	5%	0.018-0.121	2/74	3%	0.003-0.094	2/63	0%	0.004-0.110
61° to 65°	1/93	1%	0.000-0.058	3/74	4%	0.008-0.114	3/63	0%	0.010-0.133
66° to 70°	1/93	1%	0.000-0.058	2/74	3%	0.003-0.094	1/63	0%	0.000-0.085
71° to 75°	4/93	4%	0.012-0.106	2/74	3%	0.003-0.094	2/63	0%	0.004-0.110
76° to 80°	6/93	6%	0.024-0.135	3/74	4%	0.008-0.114	1/63	0%	0.000-0.085
81° to 85°	3/93	3%	0.007-0.091	2/74	3%	0.003-0.094	1/63	0%	0.000-0.085
86° to 90°	4/93	4%	0.012-0.106	3/74	4%	0.008-0.114	3/63	0%	0.010-0.133

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Table 22 presents change in best spectacle corrected visual acuity at near for eyes treated for near.

Table 22
Change in Best Spectacle Corrected Visual Acuity - Near
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 1		Month 3		Month 6		Month 9		Month 12	
Decrease > 2 lines	0/89	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Decrease 2 lines	0/89	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Decrease 1 line	11/89	12%	7/93	8%	3/93	3%	1/74	1%	0/63	0%
No Change	65/89	73%	69/93	74%	72/93	77%	62/74	84%	54/63	86%
Increase 1 line	11/89	12%	15/93	16%	16/93	17%	10/74	14%	9/63	14%
Increase 2 lines	2/89	2%	2/93	2%	2/93	2%	1/74	1%	0/63	0%
Increase > 2 lines	0/89	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Not reported	1/90	1%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Total	89/89	100%	93/93	100%	93/93	100%	74/74	100%	63/63	100%

RCS-011-PRS Source: /refractec/pres/sas/cvan_tab.sas Date Generated: 18FEB04 Data Lock: 21JUL2003

Table 23 presents change in best spectacle corrected visual acuity at distance for eyes treated for near.

Table 23
Change in Best Spectacle Corrected Visual Acuity - Distance
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 1		Month 3		Month 6		Month 9		Month 12	
Decrease > 2 lines	2/90	2%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Decrease 2 lines	1/90	1%	1/93	1%	2/93	2%	0/74	0%	0/63	0%
Decrease 1 line	33/90	37%	14/93	15%	12/93	13%	6/74	8%	5/63	8%
No Change	38/90	42%	54/93	58%	52/93	56%	42/74	57%	33/63	52%
Increase 1 line	16/90	18%	23/93	25%	24/93	26%	24/74	32%	23/63	37%
Increase 2 lines	0/90	0%	1/93	1%	2/93	2%	2/74	3%	2/63	3%
Increase > 2 lines	0/90	0%	0/93	0%	1/93	1%	0/74	0%	0/63	0%
Not reported	0/90	0%	0/93	0%	0/93	0%	0/74	0%	0/63	0%
Total	90/90	100%	93/93	100%	93/93	100%	74/74	100%	63/63	100%

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Subjects were asked to complete a questionnaire that allowed them to report any symptoms or complaints they had regarding their vision or ocular comfort following the CK® procedure. Changes in the patient symptoms reported from preoperative to 6, 9, and 12 months post-CK treatment are provided in Table 24.

Table 24
Change in Patient Symptoms from Preoperative to 6, 9, and 12 Months
Eyes Treated for Near with Intended Correction of 1.00 to 2.25 D

	Month 6						Month 9						Month 12					
	Unchanged or Better		Worse		Significantly Worse		Unchanged or Better		Worse		Significantly Worse		Unchanged or Better		Worse		Significantly Worse	
	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%
Light Sensitivity	87/90	97	3/90	3	0/90	0	73/73	100	0/73	0	0/73	0	58/61	95	3/61	5	0/61	0
Headache	89/90	99	1/90	1	0/90	0	70/72	97	2/72	3	0/72	0	60/60	100	0/60	0	0/60	0
Pain	89/90	99	1/90	1	0/90	0	72/72	100	0/72	0	0/72	0	60/60	100	0/60	0	0/60	0
Redness	90/91	99	1/91	1	0/91	0	73/73	100	0/73	0	0/73	0	61/61	100	0/61	0	0/61	0
Dryness	88/92	96	4/92	4	0/92	0	69/74	93	4/74	5	1/74	1	61/62	98	1/62	2	0/62	0
Excessive Tearing	91/91	100	0/91	0	0/91	0	73/73	100	0/73	0	0/73	0	61/61	100	0/61	0	0/61	0
Burning	90/91	99	1/91	1	0/91	0	73/73	100	0/73	0	0/73	0	61/61	100	0/61	0	0/61	0
Gritty, Scratchy, or Sandy Feeling	90/91	99	0/91	0	1/91	1	72/73	99	1/73	1	0/73	0	60/61	98	1/61	2	0/61	0
Glare	85/91	93	5/91	5	1/91	1	67/73	92	5/73	7	1/73	1	57/61	93	2/61	3	2/61	3
Halos	81/91	89	9/91	10	1/91	1	67/73	92	5/73	7	1/73	1	56/61	92	3/61	5	2/61	3
Blurred Vision	81/91	89	8/91	9	2/91	2	67/73	92	6/73	8	0/73	0	55/61	90	4/61	7	2/61	3
Double Vision	86/91	95	4/91	4	1/91	1	68/73	93	5/73	7	0/73	0	54/61	89	6/61	10	1/61	2
Fluctuation of Vision	82/91	90	8/91	9	1/91	1	70/73	96	3/73	4	0/73	0	56/61	92	4/61	7	1/61	2
Variation of Vision in Bright Light	85/91	93	4/91	4	2/91	2	69/73	95	3/73	4	1/73	1	58/61	95	3/61	5	0/61	0
Variation of Vision in Normal Light	88/90	98	1/90	1	1/90	1	71/72	99	1/72	1	0/72	0	56/60	93	3/60	5	1/60	2
Variation of Vision in Dim Light	86/90	96	2/90	2	2/90	2	69/72	96	3/72	4	0/72	0	54/60	90	3/60	5	3/60	5
Night Driving Vision Problems	87/92	95	2/92	2	3/92	3	70/74	95	2/74	3	2/74	3	58/62	94	1/62	2	3/62	5
Other Symptom	81/85	95	3/85	4	1/85	1	67/68	99	0/68	0	1/68	1	55/55	100	0/55	0	0/55	0

Note: Unchanged or Better = 1 point increase, no change, or any decrease; Worse = 2 point increase, Significantly Worse = 3 point increase or greater.

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Table 25 shows the incidence of "none," "mild," "moderate," "marked," and "very severe" for each symptom at baseline, 1 month, 6 months, and 12 months postoperative. While a clinically significant increase in postoperative symptoms was observed, the majority changed from "none" to "mild". The symptoms that reported a significant increase (>5%) from preoperative to 6 months or beyond in the "moderate" category are glare, halos, double vision, fluctuation of vision and variation of vision in dim light.

Table 25
Patient Symptoms

Subjective Responses	None	Mild	Moderate	Marked	Very Severe
Light Sensitivity					
Preop	81%	15%	3%	1%	0%
Month 1	56%	31%	10%	2%	1%
Month 6	71%	23%	6%	0%	0%
Month 12	76%	19%	5%	0%	0%
Headaches					
Preop	92%	5%	0%	1%	1%
Month 1	94%	4%	1%	0%	0%
Month 6	94%	5%	1%	0%	0%
Month 12	94%	5%	2%	0%	0%
Pain					
Preop	98%	2%	0%	0%	0%
Month 1	93%	6%	1%	0%	0%
Month 6	97%	2%	1%	0%	0%
Month 12	100%	0%	0%	0%	0%
Redness					
Preop	94%	6%	0%	0%	0%
Month 1	92%	7%	1%	0%	0%
Month 6	96%	3%	1%	0%	0%
Month 12	97%	3%	0%	0%	0%
Dryness					
Preop	84%	14%	1%	0%	1%
Month 1	67%	24%	7%	1%	1%
Month 6	71%	24%	5%	0%	0%
Month 12	79%	19%	2%	0%	0%

Table 25
Patient Symptoms (continued)

Subjective Responses	None	Mild	Moderate	Marked	Very Severe
Excessive Tearing					
Preop	96%	2%	2%	0%	0%
Month 1	93%	7%	0%	0%	0%
Month 6	96%	3%	0%	1%	0%
Month 12	97%	3%	0%	0%	0%
Burning					
Preop	97%	1%	2%	0%	0%
Month 1	92%	6%	1%	1%	0%
Month 6	92%	6%	1%	0%	0%
Month 12	100%	0%	0%	0%	0%
Gritty, Scratchy or Sandy Feeling					
Preop	92%	6%	1%	0%	0%
Month 1	82%	13%	3%	1%	0%
Month 6	88%	11%	0%	1%	0%
Month 12	97%	2%	2%	0%	0%
Glare					
Preop	94%	5%	1%	0%	0%
Month 1	64%	23%	9%	3%	0%
Month 6	65%	27%	8%	1%	0%
Month 12	73%	21%	3%	3%	0%
Halos					
Preop	96%	3%	1%	0%	0%
Month 1	69%	17%	9%	3%	2%
Month 6	72%	15%	12%	1%	0%
Month 12	74%	16%	6%	3%	0%
Blurred Vision					
Preop	81%	12%	6%	0%	1%
Month 1	47%	32%	13%	7%	1%
Month 6	59%	27%	11%	3%	0%
Month 12	68%	19%	8%	5%	0%
Double Vision					
Preop	97%	3%	0%	0%	0%
Month 1	77%	13%	6%	4%	0%
Month 6	83%	12%	4%	0%	1%
Month 12	81%	8%	10%	2%	0%

Table 25
Patient Symptoms (continued)

Subjective Responses	None	Mild	Moderate	Marked	Very Severe
Fluctuation of Vision					
Preop	94%	4%	2%	0%	0%
Month 1	51%	33%	12%	3%	0%
Month 6	65%	25%	10%	1%	0%
Month 12	69%	23%	6%	2%	0%
Variation in Vision in Bright Light					
Preop	86%	12%	2%	0%	0%
Month 1	63%	24%	9%	3%	0%
Month 6	70%	23%	2%	5%	0%
Month 12	84%	11%	3%	2%	0%
Variation in Vision in Normal Light					
Preop	95%	4%	1%	0%	0%
Month 1	70%	20%	9%	1%	0%
Month 6	75%	23%	1%	1%	0%
Month 12	81%	13%	5%	2%	0%
Variation in Vision in Dim Light					
Preop	86%	10%	3%	1%	0%
Month 1	61%	27%	9%	3%	0%
Month 6	62%	28%	5%	4%	0%
Month 12	65%	21%	10%	3%	2%
Night Driving Vision Problems					
Preop	86%	12%	2%	0%	0%
Month 1	61%	22%	10%	6%	1%
Month 6	66%	27%	4%	3%	0%
Month 12	82%	10%	3%	3%	2%
Other Symptom					
Preop	100%	0%	0%	0%	0%
Month 1	97%	0%	1%	2%	0%
Month 6	95%	1%	3%	1%	0%
Month 12	100%	0%	0%	0%	0%

XI. CONCLUSIONS DRAWN FROM THE STUDIES

The data in this application support reasonable assurance of the safety and efficacy of this device when used in accordance with the indications for use.

XII. PANEL RECOMMENDATION

On February 6, 2004, the Ophthalmic Device Advisory Panel recommended that the premarket approval application supplement for the ViewPoint™ CK System for the improvement of near vision be considered approvable with conditions. The conditions recommended by the panel were to:

1. Revise the first sentence of the indication for use statement as follows:
    - The Viewpoint CK System is indicated for the temporary induction of myopia (-1.00 D to -2.00 D) to improve near vision in the non-dominant eye of presbyopic hyperopes or presbyopic emmetropes, via spherical hyperopic treatment of 1.00 to 2.25 D.
2. Revise the patient and physician labeling.
3. Continue the clinical study out to 24 months and submit the data to FDA for review as a post market study.

XIII. CDRH DECISION

Following the panel meeting on February 6, 2004, FDA worked interactively with Refractec regarding the remaining issues. Generally, FDA agreed with the Panel's recommendations, and Refractec agreed to continue follow-up of subjects in their clinical study per the protocol out to the 24-month examination. Refractec submitted responses that adequately addressed all of FDA's concerns and labeling changes.

CDRH issued and approval order on _____.

XIV. APPROVAL SPECIFICATIONS

- Postapproval Requirements and Restrictions: see Approval Order.
- Hazards to Health from Use of the Device: see Indications, Contraindications, Warnings, Precautions, and Adverse Events in the labeling.
- Directions for Use: see labeling.